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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,285	07/03/2003	Richard Derek Iggo	604-689	5824

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,285	IGGO ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,21-23 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,21-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

The specific reference to the parent application 10/433,681 is incomplete. The phrase --, which is a 371 application of PCT/GB02/03211 filed 7/12/02-- should be inserted at the end of the paragraph inserted before the first line of the original specification.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

The application was amended by a preliminary amendment filed 7/3/03 with the application. The originally filed declaration was filed 2/20/04, after the application. This declaration does not properly identify the specification since it does not indicate that the specification was amended on 7/3/03. Also, the filing date of the '681 application (7/3/03) is incorrect on the declaration.

Claim Objections

Claims 1 and 21 are objected to because of the following informalities.: Claim 1 is poorly punctuated such that different elements of the claim run together. For example, in line 2, a comma should follow "cell" and the semi-colon in line 8 does not separate members of a list. In claim 21, "Tcf-4, RBPJK, Gli-l, HIFlalpha and" should be "Tcf-4, RBPJK, Gli-l, and HIFlalpha binding sites, and--. Tcf-4, RBPJK, Gli-l, and HIFlalpha are proteins, not DNA sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-11, 21-23, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendment to claim 1 introduces new matter into the claims. Applicant has not met their burden to indicate where the original disclosure supports the new limitations in the claims. See MPEP 714.02, last sentence of the third paragraph from the end and 2163.06 (I) last sentence.

First, claim 1 recites the limitation: "one or more of the human or animal transcription factor binding sites being inserted into the right hand inverted terminal repeat (ITR) such as to provide sufficient symmetry to allow it to base pair to the left hand ITR during replication." This feature is originally described (page 5, lines 12-26; page 7, line 23, to page 8, line 13; Fig. 1A) in

the context of an embodiment where endogenous transcription factor binding sites upstream of the E1A coding region of the adenoviral genome, including those within the 5' ITR, are replaced with exogenous transcription factor binding sites (the binding sites are not simply inserted into ITR), the packaging sequence is moved to another operable location, e.g. near the 3' ITR, and the 3' ITR is modified by making the same replacements of transcription factor binding sites as done with the 5' ITR, in order to "provide sufficient symmetry". The movement of the packaging sequence is required in the disclosed embodiment because replacement of the binding sites within the E1A enhancer would also be replacement of parts of the packaging sequence, which would inactivate the packaging sequence. Thus, the claim as written is directed to a broader genus than was described in the original disclosure because it does not include the other limitations of the originally described embodiment to which this new claim limitation pertains.

Second, claim 1 recites the limitation the viral DNA construct "further comprises wild type transcription factor binding sites for the E2 and E3 open reading frames." This limitation does not specify where these wild type binding sites are located, i.e. these binding sites need not be in their endogenous locations in the E2 and E3 regions of the wild type adenovirus DNA sequence. The specification discloses that the endogenous overlapping, divergent E2 and E3 promoter region of the adenoviral DNA may also be modified by mutations to inactivate endogenous transcription factor binding sites (E3) and/or by insertion of the exogenous human or animal transcription factor binding sites (page 6, lines 17-23), which implicitly means that they need not be modified. The specification does not disclose moving or inserting these endogenous transcription factor binding sites of the E2 and E3 regions to other locations in the construct, as is permitted by the claim as written. This part of the rejection would be overcome by amending the

claim to clearly require that the E2 and E3 transcription factor binding sites of the wild type adenovirus DNA sequence are not modified.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 21-23, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the E1A open reading frame" and "said human or animal transcription factor" in lines 4-6. There is insufficient antecedent basis for these limitations in the claim. With respect to the former, insertion --of the wild type adenoviral DNA sequence-- following "frame" would provide the antecedent basis. The amendment does not address the latter; recitation of "human or animal transcription factor binding sites" does not provide antecedent basis for "said human or animal transcription factor", binding sites and factors are different entities.

Claim 1 recites the limitations "the adenoviral fiber gene and the E4 region of the viral construct" and "the E3 promoter" in lines 14-16. There is insufficient antecedent basis for these limitations in the claim. The viral construct may have more than just "a wild type adenoviral DNA sequence" due to recitation of "comprising." This would be remedied by deleting "of the viral construct" (line 15) and inserting --in the adenoviral DNA sequence-- after "a location" in line 13.

Claim 1 recites the limitation "one or more of the human or animal transcription factor binding sites being inserted into the right hand inverted terminal repeat (ITR) such as to provide sufficient symmetry to allow it to base pair to the left hand ITR during replication." This limitation is unclear and ambiguous since the claim does not recite any modification of the left hand ITR. Consequently, it is unclear "symmetry" is being referred to or what modifications are being required in the right hand ITR, or whether the claim actually requires symmetrical modifications to the left and right hand ITRs.

Claim 4 recites the limitation "the wild type packaging signal" and "the left hand inverted repeat" in lines 1-3. There is insufficient antecedent basis for these limitations in the claim. Inserting --of the adenoviral DNA sequence-- after "signal" in line 2 would be remedial.

Claim 8 recites the limitations "the E4 promoter," "the E1A enhancer," and "the packaging signal" in lines 1-2. There is insufficient antecedent basis for these limitations in the claim.

Applicant's arguments filed 1/11/06 have been fully considered but they are not persuasive. Applicant indicates that the amendments have overcome the previous grounds of rejection. In response, the amendments have overcome some, but not all, of the grounds of rejection.

Claim Rejections - 35 USC § 102

Claims 1, 3, 4, 7, 9-11, 21, 22, and 25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Iggo et al., WO 00/56909 for the reasons of record set forth in the Office action of 7/11/05.

Applicant's arguments filed 1/11/06 have been fully considered but they are not persuasive. Applicant indicates that the amendments have overcome the previous grounds of rejection. Iggo discloses a variety of possible modifications, the preferred embodiments involve modification of the E2 and E3 promoters, but not all do. One embodiment describes altering the E1A and E4 promoter regions, as previously indicated, wherein the exogenous binding elements replace binding elements in the left and right ITRs and relocation of the packaging sequence to the E4 region, i.e. the right end.

Double Patenting

Applicant is advised that should claims 2 and 3 be found allowable, claims 23 and 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1-11, 21-23, and 25 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7, 9, 11-16, 19, 20, and 25-38 of copending Application No. 10/433,681 for the reasons of record set forth in

the Office action of 7/11/05. The claims as amended in the instant and copending applications are directed to the same disclosed embodiments, although the claims do not precisely match in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633